

DETAILED ACTION

Claim Objections

1. Claims 6 and 9 are objected to because of the following informalities: Claim 6 is objected to because "if the an orientation" appears to be grammatically incorrect. Claim 9 is objected to because "measuring a plurality of spatial positions of the first and second localizers and on orientation..." (emphasis added) appears to be grammatically incorrect. Claim 9 is also rejected because it is unclear what the phrase "on the one hand the deviation..." refers to. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Applicant discloses limitations in Claims 1 and 8 such as "a memory for storing...", "a data processing unit for correcting...", "a quality dimension including weighted components for measuring...", and "an imaging device for...". However, it is unclear whether the claim elements invoke 35 U.S.C. 112, sixth paragraph. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may:

- (a) Amend the claim to include the phrase "means for" or "step for". The phrase "means for" or "step for" must be modified by functional language, and the phrase or term must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or
- (b) Present a sufficient showing that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or

acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected because "the determination" (Line 1) and "the position" (Line 1), "the spatial position lack proper antecedent basis. Claim 1 is also rejected because it is unclear how one localizer indicates "a plurality of spatial positions". Claim 1 is further rejected because it is unclear how the "quality dimension" can perform any measurement step (e.g. measuring the deviation) since the quality dimension is merely a displacement value. Claims 5-6 are rejected because it is unclear whether "a first spatial position" of the first and second localizers are the same "spatial positions" set forth in Claim 1 (Line 4). Claim 6 is rejected because it is unclear if "an orientation" is the orientation or if "a shape of the instrument section" is the same shape set forth in Claim 1. Claim 6 is also rejected because it is unclear what the "warning message" is for since the location of the instrument has already been "corrected". Claim 9 is rejected because it is unclear how one localizer indicates "a plurality of spatial positions". Claim 9 is also rejected because "the instrument section" lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3 and 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,892,090 to *Verard et al.* "Verard".

As for Claims 1-3 and 8-10, *Verard* discloses a method and device for determining the position of an instrument in a vascular system comprising: more than one electromagnetic localizer for determining the position/orientation of the catheter with respect to external field generators (Column 2, Lines 30-35; Column 3, Lines 38-58). *Verard* further discloses an imaging device (14 in Fig. 1), configured to capture volumetric scan data, a data processing unit (16 in Fig. 1) and a display (18 in Fig. 1). *Verard* discloses wherein "*Position data such as location and/or orientation data from the tracking subsystem 20 is in turn relayed to the data processor 16. The data processor is adapted to receive position/orientation data from the tracking subsystem 20 and operable to render a volumetric perspective image and/or a surface rendered image of the region of interest*" (Column 4, Lines 8-20). Examiner notes that the region of interest includes a vessel or a cavity within the patient (Column 2, Line 67-Column 3,

Line 1). In one embodiment, *Verard discloses* wherein a “secondary image” (e.g. surface rendered image) is displayed with an indicia or graphical representation which corresponds to the location of the surgical instrument within an air passage. *Verard also discloses* wherein the surgical navigation system may also incorporate atlas maps (3D or 4D) which may be registered with patient specific scan data or generic anatomical models (e.g. heart models) (Column 7, Lines 9-16). Examiner contends that either the "secondary image" or the atlas maps registered to the image data are considered to be a "vascular map". Furthermore, to “*...enhance visualization and refine accuracy of the displayed image data, the surgical navigation system can use prior knowledge such as the segmented vessel structure to compensate for error in the tracking subsystem or for inaccuracies caused by an anatomical shift occurring since acquisition of scan data. For instance, it is known that the surgical instrument being localized is located **within** a given vessel and, therefore should be displayed **within** the vessel. Statistical methods can be used to determine the most likely location; within the vessel with respect to the reported location and then compensate so the display accurately represents the instrument within the center of the vessel*” (Column 6, Lines 52-63). Examiner contends that “compensating for error” is considered to be a correction if the instrument is located outside the vessel. Moreover, the statistical methods used by *Verard* to determine the “most likely” location would include the deviation of the measured position/orientation to the vascular layout (e.g. centerline) defined by the vascular map. It should also be

noted that if, for example, the spatial deviation is the only dimension used, then it is considered to be heavily "weighted". Moreover, the "real-time" (Column 4, Lines 35-50) tracking/correcting of the displayed representation of the surgical device is considered to be a "local" or "spatial" continuous transformation

With respect to Claim 7, Verard discloses wherein the imaging device is used during surgery (Column 2, Lines 44-64). Examiner contends this intra-operative image would "verify" a position of the medical instrument.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,892,090 to *Verard et al.* "Verard" in view of U.S. Patent No. 7,366,562 to *Dukesherer et al.* "Dukesherer".

As for Claims 4-5, *Verard* discloses a device for determining the position of an instrument in a vascular system comprising more than one electromagnetic tracking sensor attached to a medical instrument (e.g. catheter) as described above. However, *Verard* does not expressly disclose wherein the plurality of EM sensors are attached in a known relative position to one another.

Dukesherer teaches from within a similar field of endeavor with respect surgical navigation (Abstract) wherein a first localization coil is provided at a known distance from a second coil to compensate for error (Column 28, Lines 25-40).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the position of the EM coils affixed to the catheter as disclosed by *Verard* to space them at known distances from each other as described by *Dukesherer* in order to detect and compensate for localization errors. Examiner notes that it would have also been obvious to modify the statistical methods used to determine the "most likely" location as described by *Verard* to incorporate the known distance (e.g. "quality dimension") between EM sensors in order to improve the accuracy in which the device is represented within the vessel as such a modification requires nothing more than the mere combination of known prior art elements and techniques to yield

predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,892,090 to *Verard et al.* "Verard" in view of U.S. Patent No. 6,198,963 to *Haim et al.* "Haim".

As for Claim 6, *Verard* discloses a device for determining the position of an instrument in a vascular system comprising more than one electromagnetic tracking sensor attached to a medical instrument (e.g. catheter) as described above. Furthermore, *Verard* discloses using the "statistical methods" to determine if the surgical instrument has potentially punctured the vessel by determining if the reported position is too far from the centerline or the trajectory of the path traveled is greater than a certain angle (worst case 90 degrees) with respect to the vessel. Examiner notes that *Verard* does not expressly disclose outputting a warning on the display.

Haim teaches from within a similar field of endeavor with respect to locating a medical device within the body using a sensor affixed to the distal end (Column 9, Lines 18-30 and 53-60). *Haim* further teaches acquiring a vector relating to the location of the sensor and processing the vector to check for errors such as "values beyond a predetermined acceptable range" (Column 9, Line 61- Column 10, Line 10). If the measurement was not successful (e.g. beyond the

predetermined range) a warning signal is visually or audibly conveyed to the user (Column 9, Lines 45-51; Column 10, Lines 11-21).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the device for determining the position of an instrument within the body as described by Verard to visually warn the user on a display if the measured/corrected spatial location exceeds a predefined threshold as described by *Haim* in order to prevent the interventional device from breaching vessel walls and disrupting vital organs.

Response to Arguments

9. Applicant's arguments filed 09/29/2011 have been fully considered but they are not persuasive. As a preliminary matter, it should be noted that Applicant has failed to address some of the 35 U.S.C. 112 rejections set forth in the previous Office Action (06/29/2011) with respect to the antecedent basis issues in Claim 1. Moreover, Applicant's amendments submitted 09/29/2011 also appear to raise new 35 U.S.C. 112 rejections as set forth above.

With respect to the prior art rejections, particularly *Verard*, Applicant has argued that "*There is nothing in this reference that discloses correcting the captured position of the surgical instrument as substantially recited in the claims*" and that "*The only reference to correcting is found at page 7, Lines 7-9 of Verard...*". Examiner respectfully disagrees. As set forth in the rejection above, *Verard* disclose to "...enhance visualization and refine accuracy of the displayed image data, the surgical navigation

*system can use prior knowledge such as the segmented vessel structure to compensate for error in the tracking subsystem or for inaccuracies caused by an anatomical shift occurring since acquisition of scan data. For instance, it is known that the surgical instrument being localized is located **within** a given vessel and, therefore should be displayed **within** the vessel. Statistical methods can be used to determine the most likely location; within the vessel with respect to the reported location and then compensate so the display accurately represents the instrument within the center of the vessel" (Column 6, Lines 52-63). Examiner contends that "compensating for error" is considered to be a correction if the instrument is located outside the vessel. Moreover, the statistical methods used by Verard to determine the "most likely" location would include the deviation of the measured position/orientation to the vascular layout (e.g. centerline) defined by the vascular map. It should also be noted that if the spatial deviation is the only deviation used, then such a "quality dimension" is heavily "weighted".*

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER COOK whose telephone number is (571)270-7373. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. C./

/BRIAN CASLER/

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